AUG 1 6 2001

K012379

## 510(k) SUMMARY

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| Prepared: | July 23, 2001 |
| Submitter: | TREX Enterprises Corporation<br>10455 Pacific Center Court<br>San Diego, CA 92121-4339<br>Phone: 858-646-5300<br>Fax: 858-646-5301 |
| Contact Person: | Peter J. Martin, Ph.D.<br>Manager, Digital Medicine Group<br>Phone: 808-875-2616<br>Fax: 808-875-2611 |
| Establishment Registration & Device Listing: | Submitted – FDA Response Pending |
| Device Trade Name: | PDX-2000 Portable Digital X-ray System |
| Common Name: | Various Models of X-ray Systems |
| Classification: | Class II – Radiology Panel |
| Classification Name: | Mobile X-ray system. (per 21 CFR section 892.1720) |
| Product Code: | 90 IZL |
| Predicate Devices: | MinXray HF100H Portable X-ray Generator<br>Manufactured by MinXray Inc.<br>3611 Commercial Avenue<br>Northbrook, IL 60062-1822<br>90 IZL - K973712 Decision Date: 12-12-97<br><br>Canon CXDI-11 X-ray Digital Camera &<br>Canon CXDI-22 X-ray Digital Camera<br>Manufactured by Canon U.S.A. Inc.<br>One Canon Plaza<br>Lake Success, NY 11042<br>90 MQB – K 981556 & K992547 Decision Date: 10-13-99 |
| Description of Device: | The PDX-2000 Portable Digital X-ray System consists of a Canon X-ray digital camera CXDI-22 retrofit kit, a MinXray Portable Source Generator and Trex proprietary adaptations. The PDX-2000 provides diagnostic images for general radiography with portable table and upright system. |
| Intended Use of Device: | The PDX-2000 Portable Digital X-ray System provides digital image capture for conventional film/screen radiographic examinations. The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. |

Table of Comparison:

| TREX PDX-2000 | PREDICATE DEVICE |
|---|---|
| Canon CXDI-11 X-ray Digital Camera | Same |
| Canon CXDI-22 X-ray Digital Camera | Same |
| MinXray HF100H Portable X-ray Generator | Same |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 6 2001

Peter J. Martin, Ph.D.
Manager, Digital Medicine Group
Trex Enterprises Corporation
10455 Pacific Center Court
SAN DIEGO CA 92121-4339

Re: K012379
PDX 2000 Portable Digital X-Ray System
Dated: July 23, 2001
Received: July 26, 2001
Regulatory Class: II
21 CFR 892.1720/Procode: 90 IZL

Dear Dr. Martin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

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510(k) Number (if known): Not Yet Assigned

Device Name: PDX-2000

Indications for Use:

The PDX-2000 Portable Digital X-Ray System provides digital image capture for conventional film/screen radiographic examinations. The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT
And Radiological Devices

510(k) Number K012379